

**Data Evaluation Report on the Acute Oral Toxicity of Stablan to Japanese Quail (*Coturnix coturnix japonica*)**

PMRA Submission Number {.....}

EPA MRID Number 467152-11

<b>Data Requirement:</b>	PMRA Data Code	{.....}
	EPA DP Barcode	D325185
	OECD Data Point	{.....}
	EPA MRID	467152-11
	EPA Guideline	850.2100

**Test material:** Stablan

**Purity:** 465 g ai/L

**Common name:** Chlormequat chloride

**Chemical name:** IUPAC: Not reported

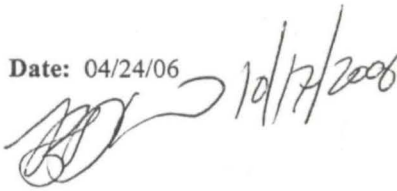
CAS name: Not reported

CAS No.: Not reported

Synonyms: Stablan (CCC)

**Primary Reviewer:** Brian D. Kiernan  
**EPA/OPP/EFED/ERBIV**

**Date:** 04/24/06



**Reference/Submission No.:** {.....}

<b>Company Code</b>	{.....}	[For PMRA]
<b>Active Code</b>	{.....}	[For PMRA]
<b>Use Site Category:</b>	{.....}	[For PMRA]
<b>EPA PC Code</b>	018101	

**Date Evaluation Completed:** 31-03-2006

**CITATION:** Hakin, B., M. Rodgers, and A.J. Norman. 1989. The acute oral toxicity (LD<sub>50</sub>) of Stablan (CCC) to the Japanese quail. Unpublished study performed by Huntingdon Research Centre Ltd., Huntingdon, Cambridge, England. Report No. LNZ 66/89691. BASF Registration Document No. 1989/1001583. Study submitted by BASF Corporation, Research Triangle Park, NC. Study initiated November 30, 1988 and submitted August 10, 1989.

**DISCLAIMER:** This document provides guidance for EPA and PMRA reviewers on how to complete a data evaluation record after reviewing a scientific study concerning the acute oral toxicity of a pesticide to avian species. It is not intended to prescribe conditions to any external party for conducting this study nor to establish absolute criteria regarding the assessment of whether the study is scientifically sound and whether the study satisfies any applicable data requirements. Reviewers are expected to review and to determine for each study, on a case-by-case basis, whether it is scientifically sound and provides sufficient information to satisfy applicable data requirements. Studies that fail to meet any of the conditions may be accepted, if appropriate; similarly, studies that meet all of the conditions may be rejected, if appropriate. In sum, the reviewer is to take into account the totality of factors related to the test methodology and results in determining the acceptability of the study.

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## EXECUTIVE SUMMARY:

The acute oral toxicity of Stablan (containing 465 g chlormequat chloride/L) to young adult (not further specified) Japanese quail (*Coturnix coturnix japonica*) was assessed over 14 days. Stablan was administered to the birds by gavage at 0 (vehicle control), 480, 686, 980, 1400, and 2000 mg product/kg bw. The 14-day-acute oral LD<sub>50</sub> (with 95% C.I.) was 1018 (862-1212) mg product/kg bw. The 14-day NOAEL of Stablan (based on mortality) was 686 mg product/kg bw. According to the US EPA classification, Stablan (containing 465 g chlormequat chloride/L) would be classified as slightly toxic to Japanese quail on an acute oral basis.

All mortality occurred within 195 minutes of dosing and totaled 0, 0, 1, 7, 6, and 10 in the 0, 480, 686, 980, 1400, and 2000 mg product/kg bw test levels, respectively. Birds in all test groups became subdued and showed unsteadiness of gait within minutes of dosing, and a number of birds were found lying on their sides prior to death. By the beginning of day 2, all surviving birds appeared to have recovered, and remained in good health throughout the rest of the study. No treatment-related effects on body weight or food consumption were observed, and no gross abnormalities were detected in any bird macroscopically examined.

This study is scientifically sound. However, as Japanese quail are not the recommended upland game bird species, this study is classified as SUPPLEMENTAL.

## Results Synopsis

Test Organism Size/Age(Mean Weight): Young adult (not otherwise specified); 154-236 g (combined sexes)

LD <sub>50</sub> : 1018 mg product/kg bw	95% C.I.: 862-1212 mg product/kg bw
Probit slope: N/A	95% C.I.: N/A
NOAEL: 686 mg product/kg bw	
Endpoint(s) Affected: mortality	

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## I. MATERIALS AND METHODS

**GUIDELINE FOLLOWED:** The study protocol was based on procedures outlined in the U.S. Environmental Protection Agency Pesticide Assessment Guidelines, §71-1 (1982). This study was submitted to fulfill the OPPTS 850.2100 guideline requirement. Deviations from OPPTS 850.2100 included:

1. Northern bobwhite quail are the recommended species for upland game bird testing.
2. The % active ingredient of chlormequat chloride in the formulated product was not reported.
3. The health of the population prior to testing (including mortality) was not reported.
4. The dosing volume was 10 ml/kg bw, exceeding the maximum guideline volume of 8 ml/kg bw.
5. A necropsy report was not provided.

**COMPLIANCE:** Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

### A. MATERIALS:

**1. Test Material** Stablan

**Description:** Yellowish-white liquid.

**Lot No./Batch No. :** 2859969

**Purity:** 465 g ai/L (not provided in terms of % purity)

**Stability of compound under test conditions:** Not reported [typically not necessary for acute oral (gavage) experiments]

**Storage conditions of test chemicals:** In the dark at -20°C

Physicochemical properties of chlorocholine chloride.

Parameter	Values	Comments
Water solubility at 20EC	Not reported	
Vapor pressure	Not reported	
UV absorption	Not reported	
pKa	Not reported	
Kow	Not reported	

(OECD recommends water solubility, stability in water and light, pKa, Pow, and vapor pressure of test compound)

### 2. Test Organism:

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**Species (common and scientific names):** Japanese quail (*Coturnix coturnix japonica*)

**Age at study initiation:** Young adult (not further specified)

**Weight at study initiation (mean and range):** 154-236 g (combined sexes)

**Source:** Mr. B. Potter, Woodhurst, Cambridgeshire, England

*(EPA recommends using either bobwhite quail or mallard duck. Birds should be at least 16 weeks old at test initiation and should be uniform in size and weight as well as phenotypically indistinguishable from wild birds).*

**B. STUDY DESIGN:**

**1. Experimental Conditions**

a. Range-finding study: An acute oral range-finding study was conducted with 2 birds/level (1/sex/level) at nominal concentrations of 1000 and 2000 mg product/kg bw. Water was used as the vehicle. A single mortality was observed at the 2000 mg product/kg bw level.

b. Definitive study

**Table 1: Experimental Parameters**

Parameter	Details	Remarks
		Criteria
<u>Acclimation</u>		
Period:	14 days	<i>The recommended acclimation period is a minimum of 15 days. OECD recommends a minimum of 7 days.</i>
Conditions: (same as test or not)	Same as test	
Feeding:	During acclimation and testing, the birds were offered standard HRC layer diet in pellet form (Batch No. 2193; Joseph Odam Ltd., Cambridgeshire, England), <i>ad libitum</i> , except for the fasting period prior to treatment	
Health: (any mortality observed)	Not reported	
Pen size and construction materials	Plastic-coated steel wire cages measuring 30 x 40 x 25 cm	



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Parameter	Details	Remarks
		Criteria
		<p><i>Pen size and construction should conform to good husbandry practices and should not create crowding stress.</i></p> <p><i>OECD recommends that pens be suitable for the captive rearing of that species.</i></p>
Test duration	14 days	<p><i>Recommended test duration is one day for dosing and at least 14 days observation.</i></p>
Dose preparation [Indicate method of confirmation of dose]	Not specified	
Mode of dose administration	Oral gavage	<p><i>Gavage or gelatin capsule is recommended</i></p>
<u>Dose levels</u>		
nominal:	0 (vehicle control), 480, 686, 980, 1400, and 2000 mg product/kg bw	<p><i>Dose levels should be a minimum of 5 treatment levels unless LD<sub>50</sub> is demonstrated to be greater than 2000 mg ai/kg</i></p>
measured:	Not reported	
<u>Solvent/vehicle, if used</u>		<p>The maximum allowable dosing volume is 8 ml/kg bw</p>
type:	Water	<p><i>The test material should be administered without a vehicle if possible. Maximum vehicle should not exceed 0.1 to 1.0% of body weight.</i></p>
amount/bw:	10 ml/kg bw	
<u>Number of birds per groups/treatment</u>		
for negative control:	N/A	<p><i>Recommended number of birds in a treatment group is 10 and 10 birds for each control and vehicle group.</i></p>
for solvent/vehicle control:	5 per sex	
for treated:	5 per sex/level	
No. of feed withholding days before dosing	Minimum of 15 hours	<p><i>Food should be withheld for at least 15 hours prior to dosing.</i></p>

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Parameter	Details	Remarks
		Criteria
<u>Test conditions</u>		
Temperature:	Min: 13 ± 2.0°C Max: 17 ± 1.6°C	The recommended photoperiod is 10 hours of light and 14 hours of dark.
Relative humidity:	73 ± 5.4%	
Photoperiod:	7 hours light/17 hours dark	
<u>Reference chemical, if used</u> name: concentrations tested:	N/A	

## **2. Observations:**

**Table 2: Observations**

Criteria	Details	Remarks
		Criteria
<u>Parameters measured</u> (mortality/individual body weight at test initiation and termination/ mean feed consumption/ others)	- Mortality - Clinical signs of toxicity - Body weight - Food consumption	Mortality was 0% in the control group.  Body weight should be measured at test initiation, on day 14 and at the end of the test if the test is extended beyond 14 days. Mortality should not be more than 10% in controls. Feed consumption should be measured as average daily food consumption.
Indicate if the test material was regurgitated	None reported.	Regurgitation is an indication that the dose was rejected. If this problem persists, the test should be repeated.

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Criteria	Details	Remarks
		Criteria
Groups on which necropsies were performed	All animals that died during the study were examined for gross pathological changes. At study termination, necropsies were performed on 10 birds from the highest surviving dose groups.	<i>Gross necropsies should be performed with inspections of the GI tract, liver, kidneys, heart, and spleen.</i>
Observation intervals	Birds were observed daily for mortality and clinical signs of toxicity. Body weights were determined weekly, and food consumption was estimated for days 1-7 and 8-14.	
Were raw data included?	Yes	

**II. RESULTS AND DISCUSSION:**

**A. MORTALITY:**

All mortality occurred within 195 minutes of dosing and totaled 0, 0, 1, 7, 6, and 10 in the 0, 480, 686, 980, 1400, and 2000 mg product/kg bw test levels, respectively. The 14-day LD<sub>50</sub> (with 95% C.I.) was reported to be 1024 (844-1237) mg product/kg bw. The slope of the line with standard error was reported to be 6.164 ± 1.451.

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**Table 3: Effect of Stabilan on Mortality of Japanese Quail.**

Treatment (mg product/kg bw )		No. of Birds	Cumulative Mortality				
			25 min	75 min	140 min	195 min	14 days
Vehicle control		10	0	0	0	0	0
480		10	0	0	0	0	0
686		10	0	1	1	1	1
980		10	4	6	6	7	7
1400		10	1	4	5	6	6
2000		10	3	10	10	10	10
NOAEL		Not reported					
LD <sub>50</sub>		1024 (844-1237) mg product/kg bw					
Reference chemical	mortality	N/A					
	LD <sub>50</sub>	N/A					
	NOAEL	N/A					

## **B. SUBLETHAL TOXICITY ENDPOINTS:**

Birds in all test groups became subdued and showed unsteadiness of gait within minutes of dosing. A number of birds were found lying on their sides prior to death. By the beginning of day 2, all surviving birds appeared to have recovered, and remained in good health throughout the rest of the study.

No treatment-related effects on body weight or food consumption were observed. Statistical comparisons were not conducted for either endpoint. All surviving birds gained weight during the week following treatment.

No gross abnormalities were detected in any bird macroscopically examined. A necropsy report was not provided.



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**Table 4: Sublethal Effect of Stablan on Japanese Quail.**

Mean Body Weight Change, g					
Treatment, (mg product/kg bw)		Males		Females	
		Days 0-7	Days 7-14	Days 0-7	Days 7-14
Vehicle control		6	6	12	11
480		9	0	10	0
686		15	5	18	-3
980		15	0	6	14
1400		6	0	17	11
2000		---(a)	---	---	---
NOAEL		Not reported		Not reported	
EC <sub>50</sub>		Not reported		Not reported	
Reference chemical	effect: NOAEL: LD <sub>50</sub> :	N/A		N/A	

Mean Feed Consumption, g/bird/day					
Treatment, (mg product/kg bw)		Days 0-7		Days 8-14	
Vehicle control		18		20	
480		20		21	
686		22		21	
980		22		22	
1400		18		18	
2000		---(a)		---	
NOAEL		Not reported			
EC <sub>50</sub>		Not reported			
Reference chemical	effect NOEL LD <sub>50</sub>	N/A			

<sup>(a)</sup> 100% mortality observed.

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**C. REPORTED STATISTICS:**

The 14-day LD<sub>50</sub> and associated 95% C.I. were calculated using the probit analysis method (Finney, 1978). No statistical analyses were applied for the endpoints of food consumption and body weight. NOAEL values were not provided for any endpoint.

**D. VERIFICATION OF STATISTICAL RESULTS:**

Statistical Method: The reviewer analyzed body weight for each observation period (days 0, 7, and 14) separately by sex. These data satisfied the assumptions of ANOVA and the NOAEL values were determined using this test. The NOAEL based on mortality was determined using Fisher's Exact test via Toxstat statistical software. The 14-day LD<sub>50</sub> was determined using the moving average method (which provided a narrower confidence interval than the Probit method) via Toxanal statistical software.

LD <sub>50</sub> : 1018 mg product/kg bw	95% C.I.: 862-1212 mg product/kg bw
Probit slope: N/A	95% C.I.: N/A
NOAEL: 686 mg product/kg bw	
Endpoint(s) Affected: mortality	

**E. STUDY DEFICIENCIES:**

There were no deficiencies that affected the scientific soundness of this study. However, several deficiencies from OPPTS 850.2100 guideline were observed. The most notable deviation was the use of Japanese quail, which is not the recommended species for acute oral toxicity testing of an upland game bird. In addition, the % ai of the formulated product was not reported. Other deviations from guidance were considered minor. Although these deficiencies do not affect the scientific integrity of the study, this study does not fulfill guideline requirements.

**F. REVIEWER'S COMMENTS:**

Results of the reviewer's statistical verification were similar to the study authors'. The reviewer's LD<sub>50</sub> value was lower than the study authors' and it was associated with a narrower confidence interval; differences are attributed to the different statistical methods used. The reviewer additionally determined a NOAEL for mortality and statistically analyzed male and female body weight for all time periods during the study (no differences from control were detected). The reviewer's results are reported in the Executive Summary and Conclusions sections.

Because the % ai of the formulated product was not provided, the LD<sub>50</sub> value in terms of ai could not be determined.

This study was conducted from November 16, 1988 (start of acclimation) to December 14, 1988.

**G. CONCLUSIONS:**

This study is scientifically sound and is thus acceptable. However, as Japanese quail are not the recommended upland game bird species, this study does not fulfill the guideline requirement as is classified as SUPPLEMENTAL.

LD <sub>50</sub> : 1018 mg product/kg bw	95% C.I.: 862-1212 mg product/kg bw
Probit slope: N/A	95% C.I.: N/A
NOAEL: 686 mg product/kg bw	
Endpoint(s) Affected: mortality	

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**III. REFERENCES:**

A reference list was not provided.

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## APPENDIX I. OUTPUT OF REVIEWER'S STATISTICAL VERIFICATION:

male body weights (day 0)

File: 5211m0 Transform: NO TRANSFORMATION

ANOVA TABLE

SOURCE	DF	SS	MS	F
Between	5	357.367	71.473	0.223
Within (Error)	24	7702.800	320.950	
Total	29	8060.167		

Critical F value = 2.62 (0.05,5,24)

Since  $F < \text{Critical } F$  FAIL TO REJECT  $H_0$ : All groups equal

male body weights (day 0)

File: 5211m0 Transform: NO TRANSFORMATION

DUNNETTS TEST - TABLE 1 OF 2

$H_0$ : Control < Treatment

GROUP	IDENTIFICATION	TRANSFORMED MEAN	MEAN CALCULATED IN ORIGINAL UNITS	T STAT	SIG
1	control	177.200	177.200		
2	480	174.200	174.200	0.265	
3	686	176.800	176.800	0.035	
4	980	167.800	167.800	0.830	
5	1400	177.200	177.200	0.000	
6	2000	171.800	171.800	0.477	

Dunnett table value = 2.36 (1 Tailed Value,  $P=0.05$ ,  $df=24,5$ )

male body weights (day 0)

File: 5211m0 Transform: NO TRANSFORMATION

DUNNETTS TEST - TABLE 2 OF 2

$H_0$ : Control < Treatment

GROUP	IDENTIFICATION	NUM OF REPS	Minimum Sig Diff (IN ORIG. UNITS)	% of CONTROL	DIFFERENCE FROM CONTROL
1	control	5			
2	480	5	26.740	15.1	3.000
3	686	5	26.740	15.1	0.400
4	980	5	26.740	15.1	9.400
5	1400	5	26.740	15.1	0.000
6	2000	5	26.740	15.1	5.400



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male body weights (day 0)

File: 5211m0 Transform: NO TRANSFORMATION

WILLIAMS TEST (Isotonic regression model) TABLE 1 OF 2

GROUP	IDENTIFICATION	N	ORIGINAL MEAN	TRANSFORMED MEAN	ISOTONIZED MEAN
1	control	5	177.200	177.200	177.200
2	480	5	174.200	174.200	175.500
3	686	5	176.800	176.800	175.500
4	980	5	167.800	167.800	172.500
5	1400	5	177.200	177.200	172.500
6	2000	5	171.800	171.800	171.800

male body weights (day 0)

File: 5211m0 Transform: NO TRANSFORMATION

WILLIAMS TEST (Isotonic regression model) TABLE 2 OF 2

IDENTIFICATION	ISOTONIZED MEAN	CALC. WILLIAMS	SIG P=.05	TABLE WILLIAMS	DEGREES OF FREEDOM
control	177.200				
480	175.500	0.150		1.71	k= 1, v=24
686	175.500	0.150		1.79	k= 2, v=24
980	172.500	0.415		1.82	k= 3, v=24
1400	172.500	0.415		1.83	k= 4, v=24
2000	171.800	0.477		1.84	k= 5, v=24

s = 17.915

Note: df used for table values are approximate when v > 20.

male body weights (day 7)

File: 5211m7 Transform: NO TRANSFORMATION

ANOVA TABLE

SOURCE	DF	SS	MS	F
Between	4	386.684	96.671	0.452
Within (Error)	14	2993.000	213.786	
Total	18	3379.684		

Critical F value = 3.11 (0.05,4,14)

Since F < Critical F FAIL TO REJECT Ho: All groups equal

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male body weights (day 7)

File: 5211m7 Transform: NO TRANSFORMATION

BONFERRONI T-TEST		TABLE 1 OF 2		Ho:Control<Treatment	
GROUP	IDENTIFICATION	TRANSFORMED MEAN	MEAN CALCULATED IN ORIGINAL UNITS	T STAT	SIG
1	control	183.400	183.400		
2	480	182.800	182.800	0.065	
3	686	188.500	188.500	-0.520	
4	980	175.000	175.000	0.687	
5	1400	176.000	176.000	0.693	

Bonferroni T table value = 2.51 (1 Tailed Value, P=0.05, df=14,4)

male body weights (day 7)

File: 5211m7 Transform: NO TRANSFORMATION

BONFERRONI T-TEST		TABLE 2 OF 2		Ho:Control<Treatment	
GROUP	IDENTIFICATION	NUM OF REPS	Minimum Sig Diff (IN ORIG. UNITS)	% of CONTROL	DIFFERENCE FROM CONTROL
1	control	5			
2	480	5	23.211	12.7	0.600
3	686	4	24.619	13.4	-5.100
4	980	2	30.705	16.7	8.400
5	1400	3	26.802	14.6	7.400

male body weights (day 7)

File: 5211m7 Transform: NO TRANSFORMATION

WILLIAMS TEST (Isotonic regression model)		TABLE 1 OF 2			
GROUP	IDENTIFICATION	N	ORIGINAL MEAN	TRANSFORMED MEAN	ISOTONIZED MEAN
1	control	5	183.400	183.400	184.643
2	480	5	182.800	182.800	184.643
3	686	4	188.500	188.500	184.643
4	980	2	175.000	175.000	175.600
5	1400	3	176.000	176.000	175.600

male body weights (day 7)

File: 5211m7 Transform: NO TRANSFORMATION

WILLIAMS TEST (Isotonic regression model) TABLE 2 OF 2

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IDENTIFICATION	ISOTONIZED MEAN	CALC. WILLIAMS	SIG P=.05	TABLE WILLIAMS	DEGREES OF FREEDOM
control	184.643				
480	184.643	0.134		1.76	k= 1, v=14
686	184.643	0.127		1.85	k= 2, v=14
980	175.600	0.638		1.88	k= 3, v=14
1400	175.600	0.730		1.89	k= 4, v=14

s = 14.621

Note: df used for table values are approximate when v > 20.

male body weights (day 14)

File: 5211m14 Transform: NO TRANSFORM

## ANOVA TABLE

SOURCE	DF	SS	MS	F
Between	4	857.923	214.481	0.830
Within (Error)	14	3615.867	258.276	
Total	18	4473.789		

Critical F value = 3.11 (0.05,4,14)

Since F < Critical F FAIL TO REJECT Ho:All groups equal

male body weights (day 14)

File: 5211m14 Transform: NO TRANSFORM

## BONFERRONI T-TEST - TABLE 1 OF 2 Ho:Control<Treatment

GROUP	IDENTIFICATION	TRANSFORMED MEAN	MEAN CALCULATED IN ORIGINAL UNITS	T STAT	SIG
1	control	189.000	189.000		
2	480	182.600	182.600	0.630	
3	686	194.000	194.000	-0.464	
4	980	175.000	175.000	1.041	
5	1400	176.333	176.333	1.079	

Bonferroni T table value = 2.51 (1 Tailed Value, P=0.05, df=14,4)

male body weights (day 14)

File: 5211m14 Transform: NO TRANSFORM

## BONFERRONI T-TEST - TABLE 2 OF 2 Ho:Control<Treatment

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GROUP	IDENTIFICATION	NUM OF REPS	Minimum Sig Diff (IN ORIG. UNITS)	% of CONTROL	DIFFERENCE FROM CONTROL
1	control	5			
2	480	5	25.512	13.5	6.400
3	686	4	27.060	14.3	-5.000
4	980	2	33.749	17.9	14.000
5	1400	3	29.459	15.6	12.667

male body weights (day 14)

File: 5211m14 Transform: NO TRANSFORM

WILLIAMS TEST (Isotonic regression model) TABLE 1 OF 2

GROUP	IDENTIFICATION	N	ORIGINAL MEAN	TRANSFORMED MEAN	ISOTONIZED MEAN
1	control	5	189.000	189.000	189.000
2	480	5	182.600	182.600	187.667
3	686	4	194.000	194.000	187.667
4	980	2	175.000	175.000	175.800
5	1400	3	176.333	176.333	175.800

male body weights (day 14)

File: 5211m14 Transform: NO TRANSFORM

WILLIAMS TEST (Isotonic regression model) TABLE 2 OF 2

IDENTIFICATION	ISOTONIZED MEAN	CALC. WILLIAMS	SIG P=.05	TABLE WILLIAMS	DEGREES OF FREEDOM
control	189.000				
480	187.667	0.131		1.76	k= 1, v=14
686	187.667	0.124		1.85	k= 2, v=14
980	175.800	0.982		1.88	k= 3, v=14
1400	175.800	1.125		1.89	k= 4, v=14

s = 16.071

Note: df used for table values are approximate when v > 20.

female body weight (day 0)

File: 5211f0 Transform: NO TRANSFORMATION

ANOVA TABLE

SOURCE	DF	SS	MS	F
Between	5	319.500	63.900	0.128



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Within (Error) 24 11969.200 498.717

Total 29 12288.700

Critical F value = 2.62 (0.05,5,24)

Since  $F < \text{Critical } F$  FAIL TO REJECT  $H_0$ :All groups equal

female body weight (day 0)

File: 5211f0 Transform: NO TRANSFORMATION

DUNNETTS TEST - TABLE 1 OF 2

$H_0$ :Control<Treatment

GROUP	IDENTIFICATION	TRANSFORMED MEAN	MEAN CALCULATED IN ORIGINAL UNITS	T STAT	SIG
1	control	193.200	193.200		
2	480	199.400	199.400	-0.439	
3	686	192.200	192.200	0.071	
4	980	193.800	193.800	-0.042	
5	1400	196.800	196.800	-0.255	
6	2000	189.200	189.200	0.283	

Dunnett table value = 2.36 (1 Tailed Value,  $P=0.05$ ,  $df=24,5$ )

female body weight (day 0)

File: 5211f0 Transform: NO TRANSFORMATION

DUNNETTS TEST - TABLE 2 OF 2

$H_0$ :Control<Treatment

GROUP	IDENTIFICATION	NUM OF REPS	Minimum Sig Diff (IN ORIG. UNITS)	% of CONTROL	DIFFERENCE FROM CONTROL
1	control	5			
2	480	5	33.333	17.3	-6.200
3	686	5	33.333	17.3	1.000
4	980	5	33.333	17.3	-0.600
5	1400	5	33.333	17.3	-3.600
6	2000	5	33.333	17.3	4.000

female body weight (day 0)

File: 5211f0 Transform: NO TRANSFORMATION

WILLIAMS TEST (Isotonic regression model)

TABLE 1 OF 2

GROUP	IDENTIFICATION	N	ORIGINAL MEAN	TRANSFORMED MEAN	ISOTONIZED MEAN
1	control	5	193.200	193.200	196.300
2	480	5	199.400	199.400	196.300

# Data Evaluation Report on the Acute Oral Toxicity of Stablan to Japanese Quail (*Coturnix coturnix japonica*)

PMRA Submission Number {.....}

EPA MRID Number 467152-11

3	686	5	192.200	192.200	194.267
4	980	5	193.800	193.800	194.267
5	1400	5	196.800	196.800	194.267
6	2000	5	189.200	189.200	189.200

female body weight (day 0)

File: 5211f0 Transform: NO TRANSFORMATION

WILLIAMS TEST (Isotonic regression model) TABLE 2 OF 2

IDENTIFICATION	ISOTONIZED MEAN	CALC. WILLIAMS	SIG P=.05	TABLE WILLIAMS	DEGREES OF FREEDOM
control	196.300				
480	196.300	0.219		1.71	k= 1, v=24
686	194.267	0.076		1.79	k= 2, v=24
980	194.267	0.076		1.82	k= 3, v=24
1400	194.267	0.076		1.83	k= 4, v=24
2000	189.200	0.283		1.84	k= 5, v=24

s = 22.332

Note: df used for table values are approximate when v > 20.

female body weight (day 7)

File: 5211f7 Transform: NO TRANSFORMATION

ANOVA TABLE

SOURCE	DF	SS	MS	F
Between	2	59.200	29.600	0.041
Within (Error)	12	8604.800	717.067	
Total	14	8664.000		

Critical F value = 3.89 (0.05,2,12)

Since F < Critical F FAIL TO REJECT Ho:All groups equal

female body weight (day 7)

File: 5211f7 Transform: NO TRANSFORMATION

DUNNETTS TEST - TABLE 1 OF 2 Ho:Control<Treatment

GROUP	IDENTIFICATION	TRANSFORMED MEAN	MEAN CALCULATED IN ORIGINAL UNITS	T STAT	SIG
1	control	205.200	205.200		
2	480	209.200	209.200	-0.236	

# Data Evaluation Report on the Acute Oral Toxicity of Stablan to Japanese Quail (*Coturnix coturnix japonica*)

PMRA Submission Number {.....}

EPA MRID Number 467152-11

3                      686              209.600                      209.600                      -0.260

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Dunnett table value = 2.11              (1 Tailed Value, P=0.05, df=12,2)

female body weight (day 7)  
File: 5211f7              Transform: NO TRANSFORMATION

DUNNETTS TEST		TABLE 2 OF 2		Ho:Control<Treatment		
GROUP	IDENTIFICATION	NUM OF REPS	Minimum Sig Diff (IN ORIG. UNITS)	% of CONTROL	DIFFERENCE FROM CONTROL	
1	control	5				
2	480	5	35.735	17.4	-4.000	
3	686	5	35.735	17.4	-4.400	

female body weight (day 7)  
File: 5211f7              Transform: NO TRANSFORMATION

WILLIAMS TEST (Isotonic regression model)		TABLE 1 OF 2			
GROUP	IDENTIFICATION	N	ORIGINAL MEAN	TRANSFORMED MEAN	ISOTONIZED MEAN
1	control	5	205.200	205.200	205.200
2	480	5	209.200	209.200	209.200
3	686	5	209.600	209.600	209.600

female body weight (day 7)  
File: 5211f7              Transform: NO TRANSFORMATION

WILLIAMS TEST (Isotonic regression model)		TABLE 2 OF 2			
IDENTIFICATION	ISOTONIZED MEAN	CALC. WILLIAMS	SIG P=.05	TABLE WILLIAMS	DEGREES OF FREEDOM
control	205.200				
480	209.200	0.236		1.78	k= 1, v=12
686	209.600	0.260		1.87	k= 2, v=12

s = 26.778  
Note: df used for table values are approximate when v > 20.

female body weight (day 14)  
File: 5211f14              Transform: NO TRANSFORM

ANOVA TABLE

**Data Evaluation Report on the Acute Oral Toxicity of Stabilan to Japanese Quail (*Coturnix coturnix japonica*)**

PMRA Submission Number {.....}

EPA MRID Number 467152-11

SOURCE	DF	SS	MS	F
Between	2	230.800	115.400	0.111
Within (Error)	12	12506.800	1042.233	
Total	14	12737.600		

Critical F value = 3.89 (0.05,2,12)

Since  $F < \text{Critical } F$  FAIL TO REJECT  $H_0$ : All groups equal

female body weight (day 14)

File: 5211f14 Transform: NO TRANSFORM

DUNNETTS TEST - TABLE 1 OF 2

$H_0$ : Control < Treatment

GROUP	IDENTIFICATION	TRANSFORMED MEAN	MEAN CALCULATED IN ORIGINAL UNITS	T STAT	SIG
1	control	215.800	215.800		
2	480	208.800	208.800	0.343	
3	686	206.600	206.600	0.451	

Dunnett table value = 2.11 (1 Tailed Value,  $P=0.05$ ,  $df=12,2$ )

female body weight (day 14)

File: 5211f14 Transform: NO TRANSFORM

DUNNETTS TEST - TABLE 2 OF 2

$H_0$ : Control < Treatment

GROUP	IDENTIFICATION	NUM OF REPS	Minimum Sig Diff (IN ORIG. UNITS)	% of CONTROL	DIFFERENCE FROM CONTROL
1	control	5			
2	480	5	43.082	20.0	7.000
3	686	5	43.082	20.0	9.200

female body weight (day 14)

File: 5211f14 Transform: NO TRANSFORM

WILLIAMS TEST (Isotonic regression model)

TABLE 1 OF 2

GROUP	IDENTIFICATION	N	ORIGINAL MEAN	TRANSFORMED MEAN	ISOTONIZED MEAN
1	control	5	215.800	215.800	215.800
2	480	5	208.800	208.800	208.800
3	686	5	206.600	206.600	206.600



# Data Evaluation Report on the Acute Oral Toxicity of Stablan to Japanese Quail (*Coturnix coturnix japonica*)

PMRA Submission Number {.....}

EPA MRID Number 467152-11

female body weight (day 14)

File: 5211f14

Transform: NO TRANSFORM

WILLIAMS TEST (Isotonic regression model)

TABLE 2 OF 2

IDENTIFICATION	ISOTONIZED MEAN	CALC. WILLIAMS	SIG P=.05	TABLE WILLIAMS	DEGREES OF FREEDOM
control	215.800				
480	208.800	0.343		1.78	k= 1, v=12
686	206.600	0.451		1.87	k= 2, v=12

s = 32.284

Note: df used for table values are approximate when v > 20.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 876.7258

## RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS
4	.1144229	1017.473	862.3692 1212.171

## RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
5	.1992997	1	.1295173

SLOPE = 6.16387

95 PERCENT CONFIDENCE LIMITS = 3.412134 AND 8.915606

LC50 = 1023.789

95 PERCENT CONFIDENCE LIMITS = 847.6822 AND 1240.77

LC10 = 637.0458

95 PERCENT CONFIDENCE LIMITS = 410.6259 AND 783.1237

## SUMMARY OF FISHERS EXACT TESTS

GROUP	IDENTIFICATION	NUMBER EXPOSED	NUMBER DEAD	SIG (P=.05)
	CONTROL	10	0	
1	480	10	0	
2	686	10	1	
3	980	10	7	*
4	1400	10	6	*
5	2000	10	10	*